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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,422	11/02/2001	Paul Polakis		7194

7590 01/06/2004
ONYX Pharmaceuticals, Inc.
3031 Research Drive
Richmond, CA 94806

EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

SM

Application No.

10/053,422

Applicant(s)

POLAKIS ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendment filed 11-3-03 has been entered. Claims 6-8 have been amended. Claims 12-17 have been added. Claims 1-17 are pending and claims 6-8 are under consideration.

It should be noted that the newly added claims 12-17 are drawn to a method of diagnosing if a suspect cell is a cancer cell by determining whether said cell has an unusual mRNA processing profile or has a mutation in its cDNA that results in a reduced level of phosphorylation of beta-catenin. Claims 12-17 are drawn to non-elected invention as evident in applicants response filed 3-25-03 to the Official action mailed 2-27-03 (Paper No. 3), therefore, claims 12-17 are withdrawn from consideration by examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 5-2-03 (Paper No. 5). Applicant's arguments filed 11-3-03 have been fully considered but they are not persuasive.

Applicants amend claims to read on cancer cells and argue that a skilled artisan would know how to analyze cancerous cells for beta-catenin levels (amendment, p. 4). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 5-2-03 (Paper No. 5). Different types of cancers differ morphologically, physiologically, and pathologically and the mechanisms of how the cancer cells grow and the gene(s) involved could vary from each other dramatically. Further, the type of biological sample used to determine the presence of wild type or mutant beta-catenin protein plays an important role in diagnosing whether a suspect cell is a cancer cell. The specification fails to provide adequate guidance and evidence whether the wild type or mutant beta-catenin protein would be present in sufficient amount in the biological sample used, such as blood, saliva, or biopsy sample from various tissues, such that said beta-catenin protein can be detected for diagnosing the cancer cells *in vitro* or *in vivo*. The specification also fails to provide adequate guidance for how to determine the presence of wild type or mutant beta-catenin protein *in vivo*, and one skilled in the art at the time of the invention would not know how to conduct the assay *in vivo* so as to diagnose whether there is a cancer cell in a patient. There is no evidence of record in the specification that the presence an elevated amount or any amount of wild type or mutant beta-catenin protein would be indicative of the presence or absence of a particular type of cancer. Longer protein half life of mutant beta-catenin protein as compared to wild type beta-catenin protein or down-regulation of wild type beta-catenin by wild type APC tumor suppressor *in vitro* does not necessarily mean that presence or any amount of wild type or mutant beta-catenin protein in any biological sample would be indicative of the

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presence or absence of a cancer cell *in vitro* or *in vivo*. Thus, claims 6-8 remain rejected under 35 U.S.C. 112 first paragraph.

Conclusion

No claim is allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. Due to the move of USPTO to new site in Alexandria, Virginia, examiner's telephone number will be changed to (571) 272-0726 **after January 12, 2004**. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in cursive script, appearing to read 's l chen', located to the right of the typed name.